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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/680,447 | 10/07/2003 | Richard G. Cornelius | 1001.1221104 | 4477 |
| 28075 | 7590 | 02/06/2006 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC | | | SZMAL, BRIAN SCOTT | |
| 1221 NICOLLET AVENUE | | | ART UNIT | |
| SUITE 800 | | | PAPER NUMBER | |
| MINNEAPOLIS, MN 55403-2420 | | | 3736 | |

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,447

Applicant(s)

CORNELIUS ET AL.

Examiner

Brian Szmal

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/15/03; 1/20/04</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 36-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a coil, does not reasonably provide enablement for a reinforcement structure or member, the reinforcement structure or member comprising a coil. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The current specification only discloses a coil on the distal and intermediate portion of the core wire, and does not disclose that the coil in the intermediate portion can be utilized as a reinforcing structure or member.

Claim Objections

3. Claim 43 is objected to because of the following informalities: There is no antecedent basis for "the reinforcement member". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3736

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 22-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Urick et al (5,666,969).

Urick et al disclose a guidewire having multiple radiopaque coils and further disclose an elongate core, wherein a distal portion of the elongate core has a first flexibility, an intermediate portion of the elongate core has a second flexibility and a proximal portion of the core that has a third flexibility, wherein the intermediate portion is proximal the distal portion and the proximal portion and proximal the intermediate portion; the first flexibility is greater than the second flexibility; an outer surface, wherein a distal portion of the outer surface has a first coefficient of friction, an intermediate portion of the outer surface has a second coefficient of friction, and a proximal portion of the outer surface has a third coefficient of friction, wherein the intermediate portion is proximal the distal portion and the proximal portion is proximal the intermediate portion; the first coefficient of friction is lower than the second coefficient of friction; the third flexibility is lower than the second flexibility; the flexibility is varied between portions of the core by varying the diameter of the core; the third coefficient of friction is higher than the second coefficient of friction; the coefficient of friction is varied between portions of the guidewire outer surface by varying the hydrophilicity of the guidewire outer surface; the distal tip is radiopaque; the distal portion of the core and the distal portion of the outer surface of the guidewire are co-extensive, the intermediate portion of the core and the intermediate portion of the outer surface of the guidewire are co-extensive, and the

Art Unit: 3736

proximal portion of the core and the proximal portion of the outer surface of the guidewire are co-extensive; a coating on a distal portion of the outer surface having a first coefficient of friction, a coating on an intermediate portion of the outer surface having a second coefficient of friction, and a coating on a proximal portion of the outer surface having a third coefficient of friction; a reinforcement structure attached along at least a portion of the guidewire; and the reinforcement structure comprises a coil wrapped around the core. See Column 3, lines 61-65; Column 4, lines 60-64; and Column 42-48 and 55-56.

Even though Urick et al does not explicitly disclose what type of coating is placed on the intermediate portion, the specification clearly states that the distal or intermediate coil can be coated with a silicone or a hydrophilic coating. Since the distal coil can be coated with a hydrophilic coating and the intermediate coil can be coated with silicone and the proximal section of the core can be coated with PTFE, Urick et al inherently discloses the above claimed limitations regarding the distal, intermediate and proximal coefficients of friction.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Avellanet et al (6,019,736), Urick (5,836,893), and Engelson (5,984,878) also disclose the use of coatings on the guidewire that have a lower coefficient of friction on the distal end and a higher coefficient of friction on the proximal end.


Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BS


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